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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,327	11/01/2000	James M. Lipton	256/019	4938

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LYON & LYON LLP
633 WEST FIFTH STREET
SUITE 4700
LOS ANGELES, CA 90071

EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/704,327

Applicant(s)
Lipton

Examiner
Randall Winston

Art Unit
1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 6 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-67 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-20, drawn to a sunburn treatment comprising of a carrier in combination with at least one polypeptide including an amino acid sequence, classified in class 530, subclass 350, for example.
 - II. Claims 21-40, drawn to a sunburn treatment kit comprising of a liquid impermeable packaging, an absorbent material, a carrier, and at least one polypeptide including an amino acid sequence, classified in class 424, subclass 59, for example.
 - III. Claims 41-55, drawn to a method of treating sunburn comprising of a carrier in combination with at least one polypeptide including an amino acid sequence wherein the carrier further includes a topical anesthetic and a skin soothing ingredient, classified in class 424, subclass 59, for example.
 - IV. Claims 61-67, drawn to a method of preventing sunburn comprising of a carrier in combination with at least one polypeptide including an amino acid sequence, classified in class 530, subclass 350, for example.
2. Inventions I (i.e. products) and III and IV (i.e. methods or use) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

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materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process using the product as claimed of Inventions III and IV can be practiced with another materially different product, such as Invention II's composition.

3. Inventions II (i.e. product) and III and IV (i.e. methods of use) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process using the product as claimed of Inventions III and IV can be practiced with another materially different product, such as Invention I's composition.

4. The products of Invention I and II are distinct, each from the other, because Invention I is drawn to a sunburn treatment comprising of a carrier in combination with at least one polypeptide including an amino acid sequence whereas Invention II is drawn to a sunburn treatment kit comprising of a liquid impermeable packaging, an absorbent material, a carrier, and at least one polypeptide including an amino acid sequence. Thus, the two different compositions would have different functions and different effects.

6. The methods of Invention III and IV are distinct, each from the other, because Invention III is drawn to a method of treating sunburn comprising of a carrier in combination with at least one polypeptide including an amino acid sequence wherein the carrier further includes a topical

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anesthetic and a skin soothing ingredient whereas Invention IV is drawn to a method of preventing sunburn comprising of a carrier (i.e. the carrier does not further include a topical anesthetic and a skin soothing ingredient) in combination with at least one polypeptide including an amino acid sequence. Thus, the two methods of treating and/or preventing are unrelated because they utilize two different products.

7. The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all the above inventions in one application.

In addition, claims 1, 21, 41 and 61 are generic to a plurality of disclosed patentably distinct species comprising (SEQ. ID. NO.1) or (SEQ. ID. NO.2) or (SEQ. ID. NO.3) or (SEQ.ID. NO.4). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication should be directed to Randall Winston at telephone number (703) 305-0404. The examiner can normally be reached during the hours of 08:30 to 17:00 Eastern.

If attempts to reach the examiner by telephone are unsuccessful, a message may be left on the voice mail. The fax number the Art 1651 (703) 308-4242 or 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. My supervisor, Michael Wityshyn, may be contacted at (703) 308-4743.

row 18 March 2002

Randall Winston
Examiner, 1651



CHRISTOPHER R. TATE
PRIMARY EXAMINER